

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Inventor(s): J. Paul GOLL

Serial No.: To Be Determined

Filing Date: Herewith

For: **NEEDLE-LESS INJECTION  
APPARATUS AND METHOD**

Group Art Unit: 3763 (Anticipated)

Examiner: M. Mendez (Anticipated)

ASSISTANT COMMISSIONER FOR PATENTS  
AND TRADEMARKS  
2900 Crystal Drive  
Arlington, VA 22202-3513

**PRELIMINARY AMENDMENT**

SIR:

Prior to examination of the above-identified application the Applicants respectfully request entry of the following amendments.

**IN THE SPECIFICATION:**

On page 1, replace the first paragraph with the following:

This is a continuation of U.S. Patent Application Serial No. 09/456,456, filed December 8, 1999. This application is related to co-pending patent application serial number 09/457,454 filed on December 8, 1999, entitled INJECTION ARRAY APPARATUS AND METHOD, co-pending patent application serial number 09/457,453 filed on December 8, 1999, entitled LATERAL NEEDLE INJECTION APPARATUS AND METHOD, and co-pending patent application serial number 09/457,193 filed on December 8, 1999, entitled LATERAL NEEDLE-LESS INJECTION APPARATUS AND METHOD.

**IN THE CLAIMS:**

Please delete claims 1-18 and add the following new claims:

19. A method of delivering a fluid to tissue of a patient, comprising:
- providing a pressurized fluid to an injection catheter comprising a shaft having a proximal end, a distal end and an infusion lumen extending therethrough, the distal end of the catheter including a nozzle and an injection port;
  - inserting the injection catheter into the patient;
  - navigating the injection catheter until the distal end is positioned adjacent to an injection site; and
  - injecting the fluid into the tissue of the patient by generating a high transient pressure in the fluid sufficient to cause the pressurized fluid to pass via the infusion lumen through the injection port and enter the tissue.
20. The method of claim 19 wherein the navigating step is performed transthoracically.
21. The method of claim 19 wherein after the injecting step is initiated, the step is performed without further operator involvement.
22. The method of claim 19 wherein the navigating step is performed intravascularly.
23. The method of claim 19 wherein the high transient pressure reaches at least 5000 psi in less than about one second.
24. The method of claim 19 wherein the high transient pressure peaks between around 4000 psi and around 7000 psi.
25. The method of claim 19 further comprising regulating a fluid flow through the catheter.
26. The method of claim 25 wherein the regulating step further comprises regulating a pressure of the flow.

27. The method of claim 19 further comprising regulating a volume of the fluid injected through the injection port.

28. The method of claim 19 further comprising the step of stabilizing the distal end adjacent to the injection site by creating a fluid seal between the tissue and the distal end.

29. The method of claim 19 further comprising positioning the injection port just below a surface of the tissue.

30. A catheter for delivering fluid to tissue of a patient, comprising:

an injection catheter comprising a shaft having a proximal end, a distal end and an infusion lumen extending therethrough;

a high pressure source for generating a high transient pressure in the fluid to be injected into the tissue; and

an injection port at the distal end of the injection catheter in fluid communication with said infusion lumen, wherein

the high pressure source is in fluid communication with the infusion lumen and is sufficient to cause the fluid to pass through the injection port and enter the tissue.

31. The catheter of claim 30 further comprising an outer sheath coaxially disposed around the shaft wherein an annular lumen is formed between an inner surface of the outer sheath and an outer surface of the shaft.

32. The catheter of claim 31 further comprising a vacuum source in fluid communication with said annular lumen wherein when the distal end of the injection catheter is place in contact with the tissue and a vacuum is applied to the annular lumen, the distal end of the injection catheter is stabilized against the tissue.

33. The catheter of claim 30 wherein the means for generating high transient pressure in the fluid comprises a syringe containing the fluid.

34. The catheter of claim 33 wherein the syringe is actuated by a mechanical actuator.
35. The catheter of claim 34, wherein the syringe is actuated pneumatically.
36. The catheter of claim 30, wherein the means for generating high transient pressure in the fluid is and automated high pressure injection system.
37. The catheter of claim 30 wherein the means for generating a high transient pressure in a fluid is a transdermal injection device.

#### REMARKS

The specification has been amended to claim priority of copending Serial No. 09/46,456, of which this is a continuation. Claims 1-18 have been deleted and new claims 19-37 have been added.


The Examiner is invited to call the undersigned at (202) 220-4232 to discuss any information concerning this application.

An Information Disclosure Statement is submitted herewith. The Information Disclosure Statement lists the references considered by the Examiner in the parent application.

The Office is hereby authorized to charge any fees under 37 C.F.R. § 1.16 or § 1.17 or to credit any overpayment to Deposit Account No. 11-0600.

Respectfully submitted,

Dated: December 10, 2001

By: 

Mark H. Neblett, Reg. No. 42,028

KENYON & KENYON  
1500 K Street, N.W., Suite 700  
Washington, DC 20005  
(202) 220-4232 (Direct)  
(202) 220-4201 (Facsimile)

**MARKED-UP VERSION OF SPECIFICATION AMENDMENT**

Page 1, first paragraph:

This is a continuation of U.S. Patent Application Serial No. 09/456,456, filed December 8, 1999. This application is related to co-pending patent application serial number 09/457,454 filed on [even date herewith] December 8, 1999, entitled INJECTION ARRAY APPARATUS AND METHOD, co-pending patent application serial number 09/457,453 filed on [even date herewith] December 8, 1999, entitled LATERAL NEEDLE INJECTION APPARATUS AND METHOD, and co-pending patent application serial number 09/457,193 filed on [even date herewith] December 8, 1999, entitled LATERAL NEEDLE-LESS INJECTION APPARATUS AND METHOD.